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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/533,493

04/29/2005

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SONN:070US

7978

32425 7590 08/06/2008
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EXAMINER

MUI, CHRISTINE T

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/533,493 | Applicant(s) SCHNETZ ET AL. | |
| | Examiner CHRISTINE T. MUI | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-42, 45-50 and 53-68 is/are rejected.
- 7) ☒ Claim(s) 43, 44, 51 and 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see REMARKS, filed 30 April 2008, with respect to the rejection(s) of claim(s) 40-68 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of USP 6,991,714 to Gauss et al.

Drawings

2. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

3. There are no drawings of records on file for this case. Please submit separate drawings for this case.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 40, 45-50, 54-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/51977 to Gauss et al.

8. USP 6,991,714 to Gauss et al (submitted on the Information Disclosure Statement on 06 October 2006; herein referred 'Gauss') is an English Translation of WO 99/15977 and is used as a basis of the rejection.

9. Regarding claims 40, 45, 46, 54, 55, 57-60 and 62-63, the reference to Gauss discloses an apparatus and method for taking samples from a polymer support. The method includes steps of using an image taking device that comprises a camera for

obtaining a digital image of the two dimensional gel with regularly or irregularly arranged dyed bands. The camera is movable as well as the adjusting device in the two dimensional gel in the reference plane. The digital image is processed in the control device and image evaluation of the markings on gel substrate of the separate bands or spots of the gel are evaluated. The bands or spots on the gel are used for punching to takes samples of and for larger bands or spots several punching steps are needed and the control devices includes a program sequence as a function of the size of the band to determine target coordinates and determines how often adjacent gel pieces are to gel taken from the band. The target coordinates refer to positions of the sample taking device relative to the band in the two dimensional gel while considering the relative coordinates of the punching capillary. After the image taking and processing or evaluation, one of the samples is automatically taken in a time sequence with the punching capillaries form the separation gel. The punching positions are irregular based on the application and are not disturbed according to the predetermined pattern. Using the adjusting device, the sample taking apparatus is arranged such that the spacing of the punching capillaries from the substrate on which the gel is located corresponds to an arranged advancing distance of the actuating means. After the digital image is taken and the target coordinates are determined, the sample taking device is moved to a position P1-P8 and a punching capillary is shot into the gel and the sample is received at the capillary end. Once the sample is taken, the sample taking device is moved to a target substrate in the form of a microtiter plate (see abstract, column 4, lines 28-column 5, line 40).

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10. Gauss does not disclose superimposing an image, but does disclose taking an image of a spot or band on the gel substrate and using this spot or band as a marking to define a desired punched area for analysis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the marked spots or bands already on the gel as a marking rather than superimposing a digital image on the surface for taking a sample of the surface to minimize the amount of equipment being used and obtain samples that are already of interest in a desired sampling area. Gauss does not disclose using a needle for punching a sample out of the surface, but discloses using a punching capillary to obtaining a sample. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sample obtaining means to be a needle rather than a punching capillary as a needle may be able to obtain a smaller sample while not ruining or damaging the surface of the substrate.

11. Regarding claims 47-48 and 50, the reference to Gauss discloses the image taking device comprises of a camera for obtaining a digital image of the two dimensional gel (see column 4, lines 28-30). It is interpreted by the examiner that the camera is capable of modify the display scale of the section of the gel as well as modify the orientation of the image of the gel that it is taking as the camera is able to move above the two dimensional gel in the reference plane parallel to the plane of the gel. Furthermore, it is interpreted by the examiner that the digital image of the spots or bands that the image taking device is able to take the digital images in color and the

colors may be modified by the camera of the control device to analyze where the spots and bands may be on the gel for analysis.

12. Regarding claim 49 and 56, the reference to Gauss discloses the spot or band on the gel to be sampled. Gauss does not disclose the spot or band to be displaced or erased, but it would have been obvious to one having ordinary skill in the art at the time the invention was made to displace or to erase the spot or band prior to sampling so that when the image taking device takes a digital image of the two dimensional gel the sample taking device only takes samples of interest in case the spots or bands are incorrectly placed on the surface.

13. Regarding claim 53, the reference to Gauss discloses the spots or bands, once punched are analyzed in microtiter (see column 5, lines 21-39). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the spot or band to also include patient information or equivalent assigned to an identifier so that one can associate or obtain additional information about the marking or band to analysis may be more efficient.

14. Regarding claim 61, the reference to Gauss discloses that once the punching capillaries are loaded, the sample taking device is moved to a target substrate in the form of microtiter plate. The sample taking device is positioned such that the ends of the punching capillaries are positioned in the respective reservoirs of the microtiter plate. The samples are deposited on the microtiter plate and are transferred into an ordered grid for further analysis (see column 5, lines 21-39). Gauss does not disclose the holes for the samples in the carrier are arranged in a pattern in the form of a binary

code, but it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the releasing sample step into the microtiter plate in a pattern in the form of a binary code so that upon analysis, there is a particular and expected pattern of the samples.

15. Regarding claim 64, the reference to Gauss discloses the samples are taken via a sample taking devices that uses a punching capillary that are in a device as seen in Figure 1. The punching capillaries are held in a holding device that comprises of a guide part that can be loaded by pressure or by a vacuum means to secure the punched-out sample into the target substrate (see column 3, lines 27-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the depth of the punching means so that one can regulate the amount of sample taken from the substrate for analysis and so that one can ensure that upon punching into the surface of the substrate the punch does not go through the entire substrate surface to the other side.

16. Regarding claim 65-66, the reference to Gauss discloses the entire apparatus is controlled by a control device that uses a program to determine the function of the size of the band, determines the coordinates and determines how often gel pieces are to be taken (see column 4, lines 45-49). Gauss does not discloses the method where the punching is started automatically after the placement of the marking, but it would have been obvious to on having ordinary skill in the art at the time the invention was made to program into the control device to start punching at a specific time once certain steps of preparing the substrate have been completed so that the entire sampling process can

be done without unnecessary human interaction. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control device so that the sampling process may be interrupted and continued in the event of improper positioning of the punching device or in the event of wanting to analyze one sample at a time to ensure quality samples and analysis.

17. Regarding claim 67, the reference to Gauss discloses the punched out samples are moved to a target substrate, in the form a microtiter plate (see column 5, lines 22-25). It is known in the art that a microtiter plate already has holes for receiving samples.

18. Regarding claim 68, the reference to Gauss discloses the sample taking device moves to positions, P1-P8, where a pneumatic cylinder is actuated so that the punching capillary is shot into the gel and the sample is received at the capillary end. Once the sample taking device has moved to all position and are sequentially loaded, they are moved to a target substrate, where they are deposited in individual reservoirs. A cleaning step in a cleaning bath is an optionally sequential step of the sample taking on the sample substrate is carried out (see column 5, lines 3-39).

19. Claims 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gauss as applied to claim 40 above, and further in view of USP 6,103,518 to Leighton (submitted on the Information Disclosure Statement on 06 October 2006; herein referred 'Leighton').

20. Regarding claims 41-42, the reference to Gauss discloses the claimed invention except for where the sample that is punched out is of a tissue sample. Leighton discloses an instrument for constructing tissue arrays. A simple, robust and precise

instrument for constructing tissue arrays includes multiple punches mounted on a punch platform. The arrays are constructed by taking samples from a series of donor tissues, one at a time, using a hollow, preferably needlelike, donor punch and placing each sample sequentially in the recipient of complementary shape in a recipient material by a recipient punch, thereby forming an array of tissues in the recipient block (see abstract, column 5, lines 1-10, column 7, lines 4-58). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a tissue sample rather than sample from a polymer support material, as a matter of design choice for intended analysis.

Allowable Subject Matter

21. Claims 43-44, 51-52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

22. A method of manipulating samples where an superimposed digital microscopic image is one that has been straightened, has artifacts removed prior to superimposing the image and the translucency of the image can be modified is not found in the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE T. MUI whose telephone number is (571)270-3243. The examiner can normally be reached on Monday-Thursday 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on (571) 272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CTM

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797